Drug Information Sheet("Kusuri-no-Shiori")

Injection
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The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: IMDELLTRA for I.V. Infusion 1mg

Active ingredient: Tarlatamab(genetical recombination)
Dosage form: injection
Imprint or print on wrapping:

Effects of this medicine

This medicine is considered to suppress the proliferation of cancer cells by binding to both CD3 expressed on the cell membrane of T cells and DLL3 expressed on the cell membrane of small cell lung cancer, activating T cells and damaging DLL3-positive tumor cells.
It is usually used to treat small cell lung cancer that has progressed after cancer chemotherapy.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults, inject by intravenous drip infusion over 1 hour once on days 1 and 8. On day 15 and thereafter, inject by intravenous drip infusion over 1 hour once every 2 weeks.
- To prevent cytokine release syndrome (CRS), corticosteroids are used within 1 hour prior to this medicine for infusion on days 1, 8 and 15. Also IV fluids are administered just after this medicine for infusion on days 1,8 and 15.
- Ask the doctor about the treatment span.

Precautions while taking this medicine

- Since CRS frequently occur early in the course of treatment, patients must be hospitalized at least for 24 hours after the infusion on days 1 and 8. Patients may also be hospitalized after the infusion on day 15 and thereafter according to the condition.
- Symptoms of CRS may include pyrexia, hypotension, hypoxia (breathing difficulty, lips turning blueish purple, etc.), fatigue, tachycardia, headache, chills, nausea, vomiting, etc. If any of these symptoms occur, contact your doctor immediately.
- Neurological events including Immune effector Cell-Associated Neurotoxicity Syndrome (ICANS) may include cognitive impairment (unable to understand words or situations, unable to recognize names of people or objects, etc.), muscle weakness (lack of muscle strength), ataxia (difficulty speaking, unable to walk straight, etc.), convulsive attack (muscle twitching in the face and limbs, temporary dawning, stiff and shivering muscle of the limbs, etc.), brain edema (dizziness, decreased vision, etc.). If any of these symptoms occur, contact your doctor immediately.
- Since neurological events including ICANS may include changes in level of consciousness and convulsive attack, patients using this medicine should pay attention when operating dangerous machinery or driving a car.
- Since cytopenia may occur, blood tests should be performed regularly before and while using this medicine.
- Patients with a possibility of getting pregnant should properly avoid pregnancy while using this medicine and for 2 months after the last use of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include cytokine release syndrome, decreased appetite, dysgeusia, pyrexia, and cytopenia. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- pyrexia, labored and fast breathing, nausea [cytokine release syndrome]

・difficulty understanding words, difficulty understanding words or situations, muscle weakness [neurological events including ICANS] ・general malaise, sudden high fever, nose bleeding [decreased blood cells] ・cough, shortness of breath/breathing difficulty, pyrexia [interstitial lung disease] **The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**
Storage conditions and other information
For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.